

K02/015 29

APR 26 2002



**510(k) SUMMARY**  
**Acist PLUS 4™ Angiographic Catheter**

**Applicant's Name and Address:**

Acist Medical Systems, Inc.  
7450 Flying Cloud Drive  
Suite 150  
Eden Prairie, MN 55344

**Name of Contact Person:**

Carl M. Beaurline  
Vice President, Quality Assurance / Regulatory Affairs

**Telephone and Fax Numbers:**

Telephone – (612) 995-9319  
Fax – (612) 941-4648

**Address of Contract Manufacturing and Sterilization Sites:**

**Manufacturing:** MedAmicus Incorporated  
15302 Highway 55 West  
Minneapolis, MN 55447

**Sterilization:** STERIS Corporation  
380 90<sup>th</sup> Avenue N.W.  
Minneapolis, MN 55433

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K021015

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**Proprietary Name:** Acist PLUS 4™ Angiographic Catheter

**Common Name:** Angiographic Catheter

**Classification Name:** Diagnostic Intravascular Catheter

**Classification Number:** 870.1200

**Class:** II

**Classification Panel:** Cardiovascular

**Product Code:** DQO

**Brief Description:**

The Acist PLUS 4™ Angiographic Catheter is intended for use in the delivery of radiopaque contrast media to selected sites in the vascular system. It is a single-lumen catheter manufactured primarily from a radiopaque plastic tube that has an encapsulated stainless steel wire braid to provide strength for injection pressures up to 8275 kPa. The proximal end of the device incorporates a strain relief with a female plastic Luer hub for injection to the injection source. The stem and tip sections are radiopaque and are permanently formed to a variety of shapes to facilitate use in various parts of the patient's vasculature. The non-tapered soft distal tip has end and multiple side-holes to balance the injection force and stabilize tip position.

The device is packaged in a Tyvek-to-poly pouch, sterilized by a validated Ethylene Oxide sterilization cycle, and sold for single use only within a 24-month shelf life.

**Predicate Device:** Acist 4 French Angiographic Catheter, K012983

**Indications for Use:**

*The Acist PLUS 4™ Angiographic Catheter is intended for use to deliver radiopaque contrast medium to selected sites in the vasculature.*



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 26 2002

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Carl M. Beaurline  
Vice President, Quality Assurance/Regulatory Affairs  
ACIST Medical Systems, Inc.  
7450 Flying Cloud Drive  
Suite 150  
Eden Prairie, MN 55344

Re: K021015  
Acist *PLUS 4*<sup>TM</sup> Angiographic Catheter  
Regulation Number: 870.1200  
Regulation Name: Diagnostic intravascular catheter  
Regulatory Class: II (two)  
Product Code: 74 DQO  
Dated: March 19, 2002  
Received: March 29, 2002

Dear Mr. Beaurline:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

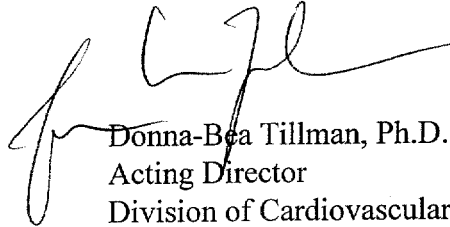
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 - Mr. Carl M. Beaurline

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Donna-Bea Tillman', is written over the typed name.

Donna-Bea Tillman, Ph.D.  
Acting Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

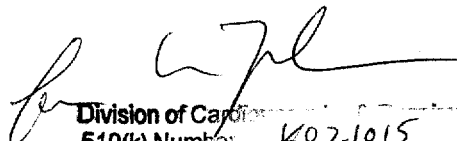
**INDICATIONS FOR USE FORM**Page 1 of 1510(k) Number: K021015Device Name: Acist PLUS 4™ Angiographic Catheter

Indications for Use:

***The Acist PLUS 4™ Angiographic Catheter is intended for use to deliver radiopaque contrast medium to selected sites in the vasculature.***

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Division of Cardiovascular Devices  
510(k) Number K021015

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐  
(Optional Format 1-2-96)